EUROPEAN
COMMISSION

Brussels, 9.12.2021
C(2021) 9442 final

COMMISSION IMPLEMENTING DECISION

of 9.12.2021

on the annual renewal of the conditional marketing authorisation for the orphan medicinal product for human use "Holoclar - Ex vivo expanded autologous human corneal epithelial cells containing stem cells", granted by Decision C(2015)1028(final)

(Text with EEA relevance)

(ONLY THE ITALIAN TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 9.12.2021

on the annual renewal of the conditional marketing authorisation for the orphan medicinal product for human use "Holoclar - Ex vivo expanded autologous human corneal epithelial cells containing stem cells", granted by Decision C(2015)1028(final)

(Text with EEA relevance)

(ONLY THE ITALIAN TEXT IS AUTHENTIC)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) and 14-a thereof,

Having regard to Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council[2],

Having regard to the application submitted by Holostem Terapie Avanzate S.r.l., on 21 July 2021, under Article 6(2) of Regulation (EC) No 507/2006 with a view to the annual renewal of the conditional marketing authorisation for the medicinal product "Holoclar - Ex vivo expanded autologous human corneal epithelial cells containing stem cells",

Having regard to the opinion of the European Medicines Agency, formulated on 14 October 2021 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "Holoclar - Ex vivo expanded autologous human corneal epithelial cells containing stem cells", entered in the Union Register of Medicinal Products under the number EU/1/14/987 and authorised by Commission Decision C(2015)1028(final) of 17 February 2015, remains in compliance with the requirements of Article 14-a of Regulation (EC) No 726/2004 of the European Parliament and of the Council, and Regulation (EC) No 507/2006,

(2) The conditional marketing authorisation granted by Decision C(2015)1028(final) should therefore be renewed.

(3) The Union Register of Medicinal Products should be updated.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 92, 30.3.2006, p. 6.

HAS ADOPTED THIS DECISION:

Article 1

The conditional marketing authorisation granted by Decision C(2015)1028(final) of 17 February 2015 is renewed without amendments.

Article 2

The period of validity of the renewed authorisation shall be one year from 19 February 2022.

Article 3

This Decision is addressed to Holostem Terapie Avanzate S.r.l., Via Glauco Gottardi 100, Modena, MO 41125, Italia.

Done at Brussels, 9.12.2021

For the Commission

Sandra GALLINA
Director-General